DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

IND 44,258

JAN 6 1994

Genelabs Technologies, Incorporated
505 Penobscot Drive
Redwood City, CA 94063

Attention: Robert M. Cohen
Director of Regulatory Affairs

Dear Mr. Cohen:

We are pleased to acknowledge receipt of your Investigational New Drug Application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act. Please note the following identifying data:

IND Number Assigned: 44,258

Sponsor: GENELABS TECHNOLOGIES, INCORPORATED

Name of Drug: GL701; Dehydroepiandrosterone (DHEA)

Date of Submission: Dec. 22, 1993

Date of Receipt: Dec. 27, 1993

IT IS UNDERSTOOD THAT STUDIES IN HUMANS WILL NOT BE INITIATED UNTIL 30 DAYS AFTER THE DATE OF RECEIPT SHOWN ABOVE. If, within the 30 day period, we notify you of serious deficiencies that require correction before human studies can begin or that would require restriction of human studies until corrected, it is understood that you will continue to withhold or restrict such studies until you are notified that the material you have submitted to correct the deficiencies is considered satisfactory.

As sponsor of this IND, you are responsible for compliance with the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder. Those responsibilities include reporting any unexpected fatal or life-threatening experiences by telephone to this Agency no later than three working days after receipt of the information (21 CFR 312.32) and the submission of annual progress reports.

Please forward all future communications concerning this IND in TRIPLICATE identified with this IND number and addressed as follows:

Pilot Drug Evaluation Staff, HFD-007
Attention: DOCUMENT CONTROL ROOM # 9B-23
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, Maryland 20857

Sincerely yours,

Dotti Beard

Project Manager
Pilot Drug Evaluation Staff
Center for Drug Evaluation and Research
(301) 443-4250